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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,470

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,470	Applicant(s) LANNIGAN-MACARA ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-18 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-18 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 15-18 and 21-24 are pending.

Claim 15 has been amended.

Claims 1-14, 19 and 20 have been cancelled.

Claims 21-24 have been added.

Claims 15-18 and 21-24 are examined on the merits.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

2. The rejection of claims 15-18 of record January 17, 2008 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants amendment to claim 15.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. The rejection of claims 15-18 and new claims 21-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained and made.

Applicants assert claim 15 fully complies with the written description requirement of 35 USC § 112 because of the amendment to the claim, see bridging paragraph of pages 4 and 5 within Remarks submitted April 17, 2008. This point of view has been carefully considered, as well as supporting arguments, but found unpersuasive.

While the Examiner concurs with Applicants regarding the specification notes on page 4, lines 20-26, human ERK8 corresponds to SEQ ID NO: 1, the language of claim 15 does not reflect such. Newly amended claim 15 includes "monitoring ERK8 levels detected by an antibody that specifically binds to the peptide of SEQ ID NO: 1...". This language is not reflective of ERK8 is one and the same as SEQ ID NO: 1. Applicants should amend the claim to read clearly such that one of ordinary skill in the art understands SEQ ID NO: 1 is ERK8 and detection and monitoring of ERK8 is the detection and monitoring of SEQ ID NO: 1. See the pending 35 U.S.C. 112, second paragraph.

The rejection is maintained for the reasons of record and present herein. Applicants may obviate the instant rejection by amending the claims to reflect that the ERK8 polypeptide of the claims reads specifically on SEQ ID NO: 1.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 15-18 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 15 and 23 are vague and indefinite because they do not clearly denote SEQ ID NO: 1 is human ERK8. The claims do not set out and define the invention with a reasonable degree of precision and particularity. Applicants may obviate the instant rejection by denoting "ERK8 (SEQ ID NO: 1)" or "SEQ ID NO: 1 (ERK8)".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. The rejection of claims 15, 16, 18 and new claims 21-24 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,759,221 (filed August 18, 2000/ IDS reference 1 submitted March 16, 2006) is maintained and made.

Applicants argue “the [patent] fails to teach monitoring the levels of ERK8, can be used to determine the effectiveness of an estrogen responsive anti-cancer therapy” and “[t]he reference is devoid of any teaching with regards to a method of contacting cancer cells with an anti-cancer agent **and then** subsequently monitoring the levels of ERK8...”, see page 6 of Remarks. These points of view have been carefully considered, but found unpersuasive.

As stated in the first action of the merits (FAOM) “[t]he patent discloses “[m]onitoring the influence of agents (e.g., drugs, compounds) on the expression or activity of kinase genes (e.g., the ability to modulate aberrant cell proliferation and/or differentiation) can be applied not only in basic drug screening but also in clinical trials. For example, the effectiveness of an agent, as determined by a screening assay as described herein, to increase or decrease kinase gene expression, protein levels, or protein activity, can be monitored in clinical trials of subjects exhibiting decreased or increased kinase gene expression, protein levels, or protein activity. In such clinical trials, kinase expression or activity and preferably that of other genes that have been implicated in for example, a cellular proliferation disorder, can be used as a marker of cellular growth and differentiation.”, see column 9, line 57-column 10, lines 54; column 46, lines 26-40; column 45, lines 37-53; column 46, line 41-column 47, line 12.

“In another embodiment, modulators of kinase expression are identified in a method in which a cell is contacted with a candidate compound and the expression of kinase mRNA or protein in the cell is determined relative to expression of kinase mRNA or protein in a cell in the absence of the candidate compound.”, see column 34, lines 42-47.

Essentially, a cell is contacted with an agent/modulator of the kinase (such as ERK8) and regarded by the Examiner as an anti-cancer agent and the level kinase protein expression is monitored and determined, see column 45, line 25 - column 48, line 12. The cells are from estrogen responsive cancers, such as breast and cervical cancers, see columns 9 and 10. The bridging paragraph of columns 46 and 47 note after administration of said agent the level of kinase protein expression is detected in samples form the treated subject. Hence, the rejection is maintained for the reasons cited herein and of record.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The rejection of claims 15-18 and new claims 21-24 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 6,759,221 (filed August 18, 2000/ IDS

reference 1 submitted March 16, 2006), and further in view of Inoue et al. (Journal of Molecular Endocrinology 29: 175-192, 2002) is maintained and made.

Applicants assert the primary reference does not teach or suggest a method of determining an anti-cancer's effectiveness against an estrogen responsive cancer cell and the secondary reference does not make up for the alleged deficiencies of the patent, see page 8 of the Remarks. These arguments have been carefully considered, but found unpersuasive.

The primary reference is anticipatory as noted in the 102(e) rejection and consequently this rejection is maintained.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
16 July 2008
/Alana M. Harris, Ph.D./

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Primary Examiner, Art Unit 1643